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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,628	08/27/2001	Patrick G. Morand	P31,360-A USA	1173

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EXAMINER	
KOPPIKAR, VIVEK D	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,628	MORAND ET AL.	
	Examiner	Art Unit	
	Vivek D. Koppikar	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/30/2007.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 24-45,53-65,67,68 and 4751 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 24-45, 4751, 53-65 and 67-68 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 24-45, 47-51, 53-65 and 67-68 are pending in this application. This communication is a Final Office Action in response to the "Amendments" and "Remarks" filed on May 30, 2007.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 24, 28-30, 33-36, 38, 42-44 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,991,729 in view of US Patent Number 6,368,797 to Schappert and in further view of "Avandel Healthcare Selects ThinkMed to Support Early Identification and Medical Management of Patients with Catastrophic Diseases" (hereinafter referred to as Avandel).

(A) As per claim 24, the combined teachings of Barry in view of Schappert in view of Avandel teach a method for identifying a research subject in a group of donors from at least one collection establishment, comprising:

a. obtaining a biological sample and medical data from a donor from a collection establishment (Barry: Col. 4, Ln. 9-12);

b. associating an identifier for said donor with said biological sample and medical data in at least a first database (Barry: Col. 4, Ln. 32-48).

c. associating the identifier for said blood donor with the name and contact information of said donor (Barry: Col. 4, Ln. 32-48)

f. matching the identifier from the first database with the name and contact information (Col. 4, Ln. 32-48).

Barry does not teach the step d. of identifying criteria for selecting a research subject nor does Barry teach the step e. of extracting an identifier from the first database, wherein said identifier is associated with a donor matching the identified criteria; however, this feature is well known in the art as evidenced by Schappert (Col. 12, Ln. 43-52). At the time of the invention it would have been obvious to one of ordinary skill in the art to have modified the method in Barry with the aforementioned feature from Schappert with the motivation of providing a powerful prognostic tool for the treatment of a disease as recited in Schappert (Col. 12, Ln. 27-33).

The combined teachings of Barry and Schappert do not teach that the purpose of the matching step (step (f)) is in order to identify a research subject nor do they teach certain criteria for a research project, however, this feature is well known in the health care industry as illustrated by Avandel, which teaches a means of identifying potentially high-risk and high-cost patients (e.g. certain criteria) from querying medical data in a database (Avandel: Paragraphs 5-6). These high-risk and high-cost patients are then recommended for management interventions (e.g. clinical or research trials). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the teachings of Barry in view of Schappert with the aforementioned teachings from Avandel with the motivation of having a means to better plan and

implement management strategies in a health maintenance organization, as recited in Avandel (Paragraph 6).

(B) As per claim 28, in the combined method of Barry in view of Schappert in view of Avandel the medical data comprises medical history data (Barry: Col. 4, Ln. 26-48).

(C) As per claim 29, in the combined method of Barry in view of Schappert in view of Avandel the medical data comprise a family history (Barry: Col. 4, Ln. 26-48).

(D) As per claim 30, in the combined method of Barry in view of Schappert in view of Avandel the medical data comprise clinical test results (Barry: Col. 4, Ln. 7-12).

(E) As per claim 33, in the combined method of Barry in view of Schappert in view of Avandel the criteria include medical history information (Barry: Col. 4, Ln. 26-48).

(F) As per claim 34, in the combined method of Barry in view of Schappert in view of Avandel the criteria include family history information (Barry: Col. 4, Ln. 26-48).

(G) As per claim 35, in the combined method of Barry in view of Schappert in view of Avandel the criteria include clinical test results (Barry: Col. 4, Ln. 9-12).

(H) As per claim 36, in the combined method of Barry in view of Schappert in view of Avandel the criteria include pharacogenomic or genomic information (Barry: Col. 4, Ln. 7-24).

(I) As per claim 38, in the combined method of Barry in view of Schappert in view of Avandel the first database is a computerized database (Barry: Col. 4, Ln. 26-29 and Ln. 48-52).

(J) As per claims 42-44, in the combined method of Barry in view of Schappert in view of Avandel the database is computerized, and the network is either an intranet or the Internet (Barry: Col. 4, Ln. 56-Col. 5, Ln. 6).

(L) As per claim 67, the combined method of Barry in view of Schappert in view of Avandel teaches the step of identifying the research subject according to claim 1 according to the selected criteria (Schappert: Col. 12, Ln. 43-52); and also teaches the step of contacting the research subject for recruiting the research subject for a clinical study (Barry: Col. 4, Ln. 26-47). The motivation for combining these two teaching is stated above in the paragraph setting forth the rejection of Claim 24.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively.

(A) As per claim 25, the combined method of Barry in view of Schappert in view of Avandel does not teach the step of obtaining informed consent from the subject, wherein the informed consent permits the medical data to be used to identify the subject as a potential research subject, however, the examiner takes Official Notice that this feature is well known in the field of patient and medical records. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have obtained informed consent from a patient before using that patient's medical records with the motivation of protecting the patient's right to privacy.

5. Claim 48 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of US Patent Application Publication 2002/0035486 to Huyn.

(A) As per claim 48, Barry teaches a plurality of biological samples collected from at least one donor (Barry: Abstract), wherein each sample is collected at a collection establishment and associated with an identifier linking the donor and the biological sample to at least one of medical data, genomic data, pharmacogenomic data, and proteomic data in at least a first database (Barry: Col. 4, Ln. 7-47). Barry does not teach that the biological samples are collected

and stored longitudinally; however, this feature is well known in the art as evidenced by Huyn (Section [0088]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the invention of Barry with the aforementioned feature from Huyn with the motivation of having a means of collecting data at either regular or irregular time intervals, as recited in Huyn (Section [0088]).

(B) As per claim 47, in the combined invention of Barry in view of Tacklind the samples are blood and blood cells (Barry: Col. 4, Ln. 7-12).

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Huyn.

(A) As per claim 49, Barry teaches a method for creating a database (Barry: Abstract), the method comprising:

a. collecting a biological sample from at least one donor from at least one collection establishment (Barry: Col. 4, Ln. 7-12);

b. collecting medical data from at least one subject (Barry: Col. 4, Ln. 7-12);

c. deriving proteomic information and genomic information from the sample (Barry: Col. 4, Ln. 22-26);

d. storing the sample in a location from which the sample can be recovered (Barry: Col. 4, Ln. 21-26);

e. associating the medical data, the proteomic information, and the genomic information with an identifier that can be used to locate the sample (Barry: Col. 4, Ln. 33-47).

Barry does not teach or suggest the step of f. of performing steps a to e on the same subject longitudinally and also does not suggest that these steps b to d are be performed in any

order; however, this feature is well known in the art as evidenced by Huyn (Section [0088]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the invention of Barry with the aforementioned feature from Huyn with the motivation of having a means of collecting data at either regular or irregular time intervals, as recited in Huyn (Section [0088]).

(B) As per claim 50, in the combined method of Barry in view of Huyn the steps a to f are performed on multiple donors (patients) (Barry: Col. 5, Ln. 28-47).

(C) As per claim 51, in the combined method of Barry in view of Huyn the biological sample is blood (Barry: Col. 4, Ln. 7-12).

(E) As per claim 53, in the combined method of Barry in view of Huyn the medical data comprises chemistry test formation (Barry: Col. 4, Ln. 16-26).

(F) As per claim 59, in the combined method of Barry in view of Huyn the medical data comprises family histories from the subjects (Barry: Col. 4, Ln. 33-47).

(G) As per claim 60, in the combined method of Barry in view of Huyn the medical data comprises demographic information from the subjects (Barry: Col. 4, Ln. 33-47).

(H) As per claim 61, in the combined method of Barry in view of Huyn the medical data comprises at least one of the medical data, the genomic information, the proteomic information, and the location for the sample is associated with an identifier for the subject that can be used to retrieve the name and contact information for the subject (Barry: Col. 5, Ln. 19-27).

7. Claims 27 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively, and in further view of US Patent Number 5,915,240 to Karpf.

(A) As per claims 27 and 68, the combined method of Barry in view of Schappert does not teach or suggest that the subject (patient) is a deferred donor, however, this feature is well known in the art as evidenced by Karpf (Col. 14, Ln. 27-34). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the combined method of Barry in view of Schappert with the aforementioned feature from Karpf with the motivation of providing a means to providing descriptions of the patient, as recited in Karpf (Col. 14, Ln. 31-33).

8. Claims 31-32, and 36-37 are rejected as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively, and in further view of US Patent Number 6,730,477 to Sun.

(A) As per claims 31-32, and 36-37 the combined method of Barry in view of Schappert does not teach that the medical data comprises pharmacogenomic, genomic or proteomic data, however, this feature is well known in the art as evidenced by Sun (Col. 6, Ln. 61-Col. 7, Ln. 8 and Col. 7, Ln. 10-23 and Col. 8, Ln. 31-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included these types of medical data in the combined method of Barry in view of Schappert with the motivation of obtaining an enhanced means of detecting, diagnosing and monitoring various diseases, as recited in Sun (Col. 3, Ln. 63-Col. 4, Ln. 4).

10. Claims 55-58 and 62-65 are rejected as being unpatentable over Barry in view of Tacklind, as applied to Claim 49, above and in further view of Sun.

(A) As per claims 55-58 and 62-65, the combined method of Barry in view of Tacklind does not teach that the medical data comprises pharmacogenomic, genomic or proteomic data as well

as the other recited types of data in these claims, however, this feature is well known in the art as evidenced by Sun (Col. 6, Ln. 61-Col. 7, Ln. 8 and Col. 7, Ln. 10-23 and Col. 8, Ln. 31-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included these types of medical data in the combined method of Barry in view of Schappert with the motivation of obtaining an enhanced means of detecting, diagnosing and monitoring various diseases, as recited in Sun (Col. 3, Ln. 63-Col. 4, Ln. 4).

9. Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert, as applied to Claims 1 and 24, above, respectively.

(A) As per claims 39-42, the combined method of Barry in view of Schappert does not teach or suggest a second computerized database stored on a separate computer and a network firewall separating the first and second computers, however, the examiner take Official Notice that this is a feature well known in the field of informational technology and computer networks. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included the above mentioned features with the motivation of providing a backup, archival data source so that vital patient data would not be destroyed if one of the computers was damaged.

Response to Arguments

10. Applicant's arguments filed on May 30, 2007 have been fully considered but they are not persuasive. Applicants arguments will be addressed in sequential order as they were set forth in the "Remarks" section dated May 30, 2007.

(1) Applicants argue that the prior art references do not teach collecting biological samples or medical data from donors of collection establishment and furthermore, that the prior art does not teach collection establishments which are defined as blood and/or plasma organizations.

However, the Office would like to point out that Barry in fact does teach the step of collecting biological samples from a patient (Barry: Col. 4, Ln. 7-11). The Office takes the position that it is inherent in this teaching that the biological sample can be collected from a wide variety of medical organization including a blood or plasma organization.

(2) Applicants argue that the prior art references do not teach matching a donor's medical data with certain criteria for a research project. However, as pointed out in the claim rejections above, Schappert does in fact teach this very feature (Schappert: Col. 6, Ln. 33-40).

(3) Applicants argue that the prior art references do not disclose matching a research identifying criteria with a name and contact information in order to identify a research subject. However, Avandel teaches this very feature (Avandel: Paragraphs 6-7). Avandel states that patients are identified so that "management interventions" can be directed at them (Avandel: Paragraph 6). The Office takes the position that a "management interventions" include research or clinical trials.

(4) Applicants argue that Huyn does not teach collecting biological samples longitudinally. However, Huyn discloses this very feature (Huyn: Section [0088]).

(5) As per the arguments against the rejection of Claims 39-42, the Applicants have not properly challenged the Office's use of Official Notice. Therefore, this rejection cannot be withdrawn.

(6) The Office acknowledges that on May 14, 2007 Marc Segal, the applicants' attorney called the Office because of some typos in the Office Action. At this time, the Office clarified the typos. However, the Examiner of record does not recall that the next Office Action would be made non-final. As per Office practice, a subsequent Office Action is made Final when there is

not a new basis of claim rejection or when the claims have been amended. In this case, the claims have been amended and there is not a new basis of claim rejection. Therefore, this Office Action must be made Final.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

7/26/2007

C. LUKE GILLIGAN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3600